REMARKS/ARGUMENTS

Applicants respectfully request reconsideration of this application. Applicants thank Examiner Soroush for his time in a telephonic conference on December 16, 2009.

By the amendments, Applicants do not acquiesce to the propriety of any of the Office's rejections and do not disclaim any subject matter to which Applicants are entitled. *Cf. Warner Jenkinson Co. v. Hilton-Davis Chem. Co.*, 41 U.S.P.Q.2d 1865 (U.S. 1997).

In the Claims

Claims 23-26 and 40-49 are pending in this application. Claims 1-22, 27-39 and 50-54 have been previously canceled.

Claim 24 has been amended to correct a typographical error.

Claims 55 and 56 are newly added and find support throughout the specification, for example in paragraphs [0053] to [0054] of the published application.

No new matter has been introduced as a result of the claim amendments.

35 U.S.C. §103 Rejections

Claims 23-26 and 40-49 have been rejected under 35 USC §103(a) as being allegedly unpatentable over Milstein (US 5,693,338), in view of Laube et al. (US 5,320,094). Office Action ("OA") mailed Sept. 16, 2009, pages 2-3.

Applicant's claims are drawn to dry powder compositions delivered to the pulmonary system using a dry powder inhaler. The Office has cited Milstein for its teaching of a delivery composition comprising an active agent and a diketopiperazine. OA, page 3. The Office acknowledges that Milstein lacks a teaching wherein the microparticles are administered from a dry powder inhaler. OA, page 3. The Office asserts that this deficiency is cured by Laube. OA, page 4. Applicants respectfully disagree that the Office has established *prima facie* obviousness of the pending claims over the combination of Milstein and Laube.

To maintain a proper rejection under 35 U.S.C. §103, the Office must meet four conditions to establish a *prima facie* case of obviousness. First, the Office must show that the prior art suggested to those of ordinary skill in the art that they should make the claimed composition or device or carry out the claimed process. Second, the Office must show that the prior art would have provided one of ordinary skill in the art with a reasonable expectation of success. Both the suggestion and the reasonable expectation of success must be adequately founded in the prior art and not in an applicant's disclosure. Third, the prior art must teach or suggest all the claim limitations. *In re Vaeck,* 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991). Fourth, if an obviousness rejection is based on some combination of prior art references, the Office must show a suggestion, teaching, or motivation to combine the prior art references ("the TSM test"). *In re Dembiczak,* 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999). Following *KSR Int'l Co. v. Teleflex, Inc.*, this fourth prong of the *prima facie* obviousness analysis must not be applied in a rigid or formulaic way such that it becomes inconsistent with the more flexible approach of *Graham v. John Deere*, 383 U.S. 1, 17-18 (1966); 127 S. Ct. 1727 (2007). It must still be applied, however, as the TSM test captures the important insight that "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *Id.* at 1741 (citing *United States v. Adams*, 383 U.S. 39, 50-52 (1966)).

Milstein teaches microsphere compositions comprising diketopiperazines and active agents. Milstein discloses administering the disclosed microspheres in a carrier fluid (such as isotonic solution) parenterally, intravenously, intramuscularly or subcutaneously (Milstein, column 8, lines 48-61). Milstein does not disclose pulmonary administration of the microspheres, or any formulation of microparticles, in a dry powder form wherein the carrier is air.

The Office stated that Laube was included for its teaching of microparticle administration from a dry powder inhaler. Laube teaches methods of delivering a protein, in particular insulin, to the lungs (Laube, abstract). Laube teaches administering insulin by aerosol from solutions of pork insulin (column 4, lines 59-64).

Laube also does not disclose pulmonary administration of any composition in a dry powder form wherein the carrier is air from a dry powder inhaler.

The Office states on page 5 of the Office Action that "[i]t would have been obvious to one of ordinary skill in the art that the active microparticles are formed into a dry powder prior to aerosolization." Applicants can find no disclosure in either Milstein or Laube which suggests that the active microparticles are present in a dry powder form prior to aerosolization. Furthermore, it is clear from the teachings of both Milstein and Laube, that the disclosed compositions are administered in a liquid form (an aerosolized liquid in Laube and a solution for parenteral, intravenous, intramuscular or subcutaneous administration in Milstein), not as a dry powder as suggested by the Office.

Furthermore, while Laube uses the term aerosol to describe the delivery form, the aerosol of Laube is delivered using a nebulizer (column 6, lines 45-47). A nebulizer "is a machine that changes liquid medicine into fine droplets (in aerosol or mist form) that are inhaled through a mouthpiece or mask. Nebulizers can be used to deliver bronchodilator (airway-opening) medicines such as albuterol, as well as anti-inflammatory medicines (Pulmicort Respules®). A nebulizer might be used instead of a metered dose inhaler (MDI). It is powered by a compressed air machine and plugs into an electrical outlet." (http://my.clevelandclinic.org/disorders/Asthma/hic_Asthma_Glossary.aspx). By definition, a nebulizer delivers a liquid medication. According to Wikipedia, nebulizers accept their medicine in the form of a liquid solution, which is often loaded into the device upon use. (http://en.wikipedia.org/wiki/Nebulizer)

Therefore, contrary to the Office's assertions, the combination of Laube and Milstein do not teach or suggest the limitations of the pending claims, particularly the administration of active agent containing microparticles in a dry powder form (in air) from a dry powder inhaler.

Applicants therefore respectfully assert that the Office has not established *prima facie* obviousness of the pending claims and request that the Office withdraw the rejection on this basis.

CONCLUSIONS

In light of the foregoing, Applicants respectfully assert that the pending claims are in condition for allowance and request that a timely Notice of Allowance be issued in this case.

The Commissioner is authorized to charge any fee which may be required in connection with this Amendment to deposit account No. 50-3207.

Respectfully submitted,

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